PATENT
2005-1001

IN THE U.S. PATENT AND TRADEMARK OFFICE

In re application of

Willem Johan VAN DER GIESSEN et al. Conf. 9285

Application No. 10/089,460 Attention: Group Director

Filed April 1, 2002 Group 1615

INTRALUMINAL DEVICE, COATING FOR SUCH DEVICE, AND METHOD FOR PREPARING SAID DEVICE

PETITION TO WITHDRAW HOLDING OF ABANDONMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

April 13, 2009

Sir:

Withdrawal of the holding of abandonment in the above-identified application pursuant to 37 CFR §1.181 is respectfully requested for the following reasons:

Recently, the undersigned attorney received from the United States Patent and Trademark Office (USPTO) a Notice of Abandonment dated February 11, 2009, in the above-identified application. The Notice indicated that the application had been abandoned in view of applicants' failure to respond to the Office Letter mailed on August 18, 2009.

Section 503 of the Manual of Patent Examining Procedure clearly states that a receipt which itemizes and properly identifies the papers which are being filed serves as *prima facie* evidence of receipt in the USPTO of all the items listed thereon on the date stamped thereon by the USPTO.

A careful review of the accompanying EFS receipt (ID No. 4816270), which contains all the necessary identifying data, reveals that on February 18, 2009, applicants timely filed an amendment in response to the Official Action of August 18, 2009, along with a petition for extension of time for three months, an authorization to charge the fees to counsel's credit card, and an authorization to credit any overpayment or pay any additional fees to counsel's deposit account.

Since the receipt bears the USPTO's EFS ID, receipt date, and time stamp, it is respectfully requested that the holding of abandonment be withdrawn, and that the application be forwarded to the Examiner for consideration of applicants' response which was timely filed on February 18, 2009.

A copy of the complete response which was previously filed on February 18, 2009, and which was apparently misplaced by the USPTO accompanies this petition.

Respectfully submitted,

YOUNG & THOMPSON

/Robert E. Goozner/

Robert E. Goozner, Reg. No. 42,593
209 Madison Street, Suite 500
Alexandria, VA 22314
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

REG/abs

Electronic Acknowledgement Receipt

EFS ID:	4816270
Application Number:	10089460
International Application Number:	
Confirmation Number:	9285
Title of Invention:	Intraluminal device, coating for such device, and method for preparing said device
First Named Inventor/Applicant Name:	Willem Johan Van Der Giessen
Customer Number:	00466
Filer:	Benoit Castel/Joni Ralls
Filer Authorized By:	Benoit Castel
Attorney Docket Number:	2005-1001
Receipt Date:	18-FEB-2009
Filing Date:	01-APR-2002
Time Stamp:	16:55:30
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1330
RAM confirmation Number	2243
Deposit Account	250120
Authorized User	GOOZNER,ROBERT E.

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. 1.492 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2009-02-18_Amendment.pdf	50550 df39ccff409bceacb2e2a019a41675d9c8f6f933	yes	11

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Claims	2	6
Applicant Arguments/Remarks Made in an Amendment	7	11

Warnings:

Information:

2	Fee Worksheet (PTO-06)	fee-info.pdf	31984 34a45958fc0d052a887e62d2aea48ac17befd66e	no	2

Warnings:

Information:

Total Files Size (in bytes):	82534

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

MAIL STOP AMENDMENT
PATENT
2005-1001

IN THE U. S. PATENT AND TRADEMARK OFFICE

In re application of

Willem Johan VAN DER GIESSEN et al. Conf. 9285

Application No. 10/089,460 Group 1615

Filed: April 1, 2002 Examiner Carlos AZPURU

INTRALUMINAL DEVICE, COATING FOR SUCH DEVICE,
AND METHOD FOR PREPARING SAID DEVICE

AMENDMENT

Assistant Commissioner for Patents February 18, 2009
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the non-final Office Action mailed August 18, 2008, for which the period for response has been extended three months, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 7 of this paper.

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

1. (currently amended) An intraluminal device, suitable for implantation in a body, which device is provided with a synthetic coating, wherein the synthetic coating comprises:

50-97% heparan sulfate;

1-20% laminin; and

0.2-15% type IV collagen.

2. (currently amended) The intraluminal device according to claim 1, wherein the coating synthetic comprises:

75-95% heparan sulfate;

3-10% laminin; and

0.5-10% type IV collagen.

3. (canceled)

4. (currently amended) The intraluminal device according to claim 1, wherein the synthetic coating further comprises a growth factor.

5. (previously presented) The intraluminal device according to claim 4, wherein the growth factor is selected from the group consisting of bFGF, IGF, TGF-β and VEGF.

6. (currently amended) An intraluminal device, suitable for implantation in a body, the device being provided with a synthetic coating that comprises:

50-97% heparan sulfate;

1-20% laminin;

0.2-15% type IV collagen; and

an antibiotic.

7. (currently amended) An intraluminal device, suitable for implantation in a body, the device being provided with a synthetic coating that comprises:

50-97% heparan sulfate;

1-20% laminin;

0.2-15% type IV collagen; and

an antibiotic comprising gentamycine.

8. (currently amended) The intraluminal device according to claim 1, wherein the synthetic coating further comprises vitronectine.

9. (currently amended) The intraluminal device according to claim 1, wherein the synthetic coating comprises:

85-95% heparan sulfate;

5-6% laminin;

3-4% type IV collagen;

0.5-1.5% entactin and nidogen;

0.001-1% growth factors; and

0.001-1% antibiotic.

10. (previously presented) The intraluminal device according to claim 1, wherein the intraluminal device is a prosthesis that comprises a stent or a graft.

11. (previously presented) A coating suitable for the intraluminal device according to claim 1.

12. (currently amended) A method for preparing an intraluminal device, comprising the steps of:

- providing an intraluminal device for implantation in a body;

- preparing a synthetic composition, comprising, in about 50 mg/ml solvent:

50-97% heparan sulfate;

1-20% laminin;

0.2-15% type IV collagen; and

the solvent being a suitable buffer or water;

- dipping the intraluminal device in the composition; and

- drying the dipped intraluminal device.

13. (currently amended) The method according to claim 12, wherein the synthetic composition further comprises entactin and nidogen.

14. (currently amended) The method according to claim 12, wherein the synthetic composition further comprises a growth factor, selected from the group consisting of bFGF, IGF, TGF-β and VEGF.

15. (currently amended) The method according to claim 12, wherein the synthetic composition further comprises an antibiotic.

16. (currently amended) The method according to claim 12, wherein the synthetic composition further comprises vitronectin.

17. (currently amended) The method according to claim 12, wherein the synthetic composition comprises:

85-95% heparan sulfate;

5-6% laminin;

3-4% type IV collagen;

0.5-1.5% entactin and nidogen;

0.001-1% growth factors; and

0.001-1% antibiotic.

18. (currently amended) The intraluminal device according to claim 1, wherein the synthetic coating further comprises entactin and nidogen.

REMARKS

The Examiner is thanked for the thorough examination of the application.

Claims 1, 2 and 4-18 are pending in the application. The claims have been amended to set forth the synthetic nature of the present invention.

No new matter is believed to be added to the application by this amendment.

Rejection Under 35 USC §103(a)

Claims 1, 2, 4-6 and 8-18 have been rejected under 35 USC §103(a) as being unpatentable over SCHNEIDER et al. (Journal of Vascular Surgery). Traversal of this rejection is respectfully maintained for at least the reasons set forth below.

Independent claims 1 and 12 of the present invention recite a synthetic coating or composition that includes 50-97% heparan sulfate, 1-20% laminin and 0.2-15% type IV collagen.

SCHNEIDER et al. has been discussed in previous responses.

As as been noted, there is no disclosure whatsoever in SCHNEIDER et al. that the constituents of the present invention are present in the synthetic coating at the specific claimed concentrations.

The article by SCHNEIDER et al. clearly does not describe a synthetic coating, but instead describes a naturally produced coating. Moreover, there is no disclosure whatsoever in

SCHNEIDER et al. that the consitituents according to the present invention are present in the specific claimed concentrations of the present invention.

More specifically, SCHNEIDER et al. fail to disclose the use of heparan sulphate (50% or greater) as a major component in the synthetic coating in order to prevent thrombosis. Therefore independent claims 1 and 12 of the present invention are clearly patentable over SCHNEIDER et al.

Furthermore, in view of the ***natural*** nature of the related art coatings, it is not obvious for the skilled person to interfere with nature in order to vary the amounts of the constituents in this coating, specifically to reach the amounts according to the present invention.

On page 655, left column, last paragraph, SCHNEIDER et al. demonstrate the importance of the natural nature of the coating, because the "***naturally*** produced ECM" supposedly has "superior cell growth-promoting properties" when compared with "isolated constituents of the ECM". Therefore, SCHNEIDER et al. teaches away from using a coating with specifically selected substituents departing from nature.

Moreover, SCHNEIDER et al. is concerned with a coating that improves adhesion and growth of ECs on synthetic graft material. In practice, the bare coating of SCHNEIDER et al. appears to have a proliferative effect with an enhanced probability of thrombosis. Not surprisingly, Schneider teaches to

expose the coating to glutaraldehyde or to seed vascular ECs to the coating to create a nonthrombogenic surface to prevent thrombosis. There is no disclosure or suggestion in SCHNEIDER et al. to modify the ECM in an attempt to improve the anti-thrombotic properties.

As a result, one of ordinary skill in the art would not be motivated by SCHNEIDER et al. to produce a claimed embodiment of the present invention. A *prima facie* case of unpatentability has not been made. This rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

Rejection Under 35 USC §112, First Paragraph

Claims 1-18 have been rejected under 35 USC §112, first paragraph as failing to comply with the written description requirement. This rejection is respectfully traversed.

At page 4 the Official Action asserts:

> *"Applicant claims a specific formulation of laminin, collagen Type IV, and heparin sulfate at specific percentages. However, the specification never sets out the naturally occurring percentage of each component. Without this information, it is impossible to convey that the applicant did not merely used the naturally occurring percentage of each clarification is requested."*

However, the claimed invention now sets forth that the coating or composition is ***synthetic***. This limitation is supported at, e.g., page 6, line 20 reciting "Preparing a composition, comprising in about 50 mg,ml solvent . . .", which clearly infers

that the a synthetic compostion as opposed to being purified or isoloted or obtained from a naturally obtained product.

Also note the dependent claims, which claim antibiotics for example, which clearly would not arise from a natural sample.

The assertion that the specification set forth the naturally occurring amount of the components is thereby rendered moot in light of the amended claims.

This rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

Notice of Abandonment

The Notice of Abandonment mailed February 11, 2009 was premature. Withdrawal thereof is respectfully requested.

Conclusion

The rejections have been overcome, obviated or rendered moot. No issues remain. The Examiner is accordingly respectfully requested to place the application in condition for allowance and to issue a Notice of Allowability.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

/Robert E. Goozner/

Robert E. Goozner, Reg. No. 42,593
Customer No. 00466
209 Madison Street, Suite 500
Alexandria, VA 22314
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

REG/jr